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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,463	09/12/2003	Andreas Hartlep	SCHWP0176USA	7155

7590 04/11/2007

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EXAMINER	
SHAHRESTANI, NASIR	
ART UNIT	**PAPER NUMBER**
3737	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,463	HARTLEP ET AL.	
	Examiner	Art Unit	
	Nasir Shahrestani	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-12,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-12,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 12/05/2006 have been fully considered but they are not persuasive.

Applicant argues that the disclosure of Kucharczyk does not include function imaging for the use of navigation. However, as stated in the previous office action dated 07/05/2006, the examiner states that Kucharczyk discloses functional imaging (col. 11, lines 55-63). Kucharczyk states that the method provides for "real-time imaging of brain function and heart function during interventional endovascular procedures, particularly where interventional devices such as catheters are...directed sequentially through one or more organs or body parts to perform a diagnostic or therapeutic procedure" (col. 11). Further, Kucharczyk states that "image" means data that represents "the spatial layout of anatomical or functional features of a patient" (col. 12, lines 18-20) and that "registration" means an alignment process by which two images are positioned coincident with each other so that corresponding points appear in the same position on the registered images (col.12, lines 27-30). Therefore, it is understood that Kucharczyk does in fact disclose these features.

Further, Applicant argues that the disclosure of Kucharczyk does not teach the registering and/or referencing the position of the hyper/hypometabolic cortical areas with respect to the position of the stimulator. Examiner however respectfully disagrees in that the method of

Kucharczyk is capable of detecting brain function (col. 11, lines 55-63) and, therefore, would be capable of detecting hyper/hypometabolic cortical areas.

Regarding applicant's argument relating to claim 15, examiner respectfully disagrees in the disclosure of Kucharczyk (col. 13 lines 12-40) does in fact teach the limitation of "simulating a field distribution for a stimulation coil relative to a position of the stimulation coil" based on the fact that the "computer may also be electronically associated with the magnetic stereotaxis" by which within the broadest reasonable interpretation, meets the aforementioned limitation of claim 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 8-12 and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk, et al (US 6298259) in view of Howard, III (US 6129685) and further in view of Howard, III (US 5820588). The invention of Kucharczyk discloses the invention substantially as claimed except for the invention being related to planned stimulation with specific regard to the manifestation of systemic tinnitus. Kucharczyk discloses a method for planning the stimulation of cortical regions including imaging structural features (col. 2, lines 24-29) and imaging functional regions (col.11, lines 55-63). The method of Kucharczyk is capable of

detecting brain function (col. 11, lines 55-63) and, therefore, would be capable of detecting hyper/hypometabolic cortical areas. Kucharczyk discloses registration of image sets (col 17, lines 28-33) and referencing the position of different cortical areas as part of a medical navigation system (col. 17, lines 13-17; col. 17, lines 33-49). In light of such detection, it would have been obvious to one of ordinary skill in the art to have positioned the stimulator relative to cortical areas as detected. The invention of Kucharczyk is capable of planned stimulation. Kucharczyk discloses the navigation system as being capable of magnetically detecting positional coils (col. 17, lines 17-28). Kucharczyk discloses a medical probe capable of cortical stimulation (col. 12, lines 6-16). Kucharczyk discloses the method as determining navigation data as well as targeted or optimal regions for stimulation wherein a computer manages the data output (col. 17, lines 4-8; col. 11, lines 16-21) and wherein the computer has a storage medium (col. 14, line 66- col .15, line 3). Kucharczyk discloses stimulation a field distribution and determining stimulation areas (col. 13, lines 12-40). Kucharczyk discloses calibrating the probe within the framework of planning, i.e. determining the initial position of the probe (col. 16, line 18-20). Kucharczyk discloses that the use of optical imaging in surgical navigation (col. 10, lines 38-43).

Howard, III (5820588) discloses a method for stimulation of regions in the auditory cortex in order to reduce the effects of tinnitus (col. 7, lines 42-45).

Howard, III (6129685) discloses a method for planning stimulation of cortical regions including the primary auditory cortex wherein an electrode assembly having a magnetic tip is moved into a desired position within the target tissue by application of a magnetic field outside the patient's boy (col. 12, lines 24-31). Howard discloses a method for determining physiological

patient data via this imaging method (col. 20, lines 49-63) and would be capable of detecting positions of the hyper/hypometabolic cortical areas. Howard discloses methods for determining anatomical data and the position of the stimulator (col. 12, lines 50-56). Howard discloses methods for stimulation of localized regions of the auditory cortex (col.14, lines 56-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have combined the planned stimulation surgical method of Kucharczyk with the teachings of Howard, III such that the method included planned stimulation of areas related to systemic tinnitus for the purpose of delivering electrical signals in order to reduce clinically significant auditory phenomena caused by tinnitus, a disorder that affects 9 million Americans with 2 million of those being severely disabled by the disorder (Howard, III (5820588), col 6, lines 36-45).

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk in view of Howard, III as applied to claim 1 above, and further in view of Hochman (US 6196226). The modified invention of Kucharczyk, as discussed above, substantially discloses the invention as claimed except for the functional image detection method including at least one of a functional magnetic resonance image detection and a positron emission tomography (PET) and the methods including optical navigation. Hochman discloses methods including optically identifying and providing information regarding areas of cortical activity that could aid in the positioning of a probe or stimulator (col. 4, lines 25-35). Hochman discloses the use of magnetic resonance (col. 22, lines 17-21; col. 12, lines 56-65)and discusses determining functional information from cortical areas (col. 4, lines 8-12), rendering it obvious to apply functional magnetic resonance for the same purpose. Therefore, it would have been obvious to

one of ordinary skill in the art at the time of the invention to have combined the planned stimulation surgical methods of Kucharczyk with the teachings of Hochman such that the methods included the use of functional magnetic resonance imaging and optical navigation and detection of markers for the purpose of being able to properly position the stimulator probe to the cortical area of interest and obtain the desired physiologic result.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nasir Shahrestani whose telephone number is 571-270-1031. The examiner can normally be reached on Mon.-Thurs: 7:30-5:00, 2nd Friday: 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NS
3/31/2007

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